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EXAMINER
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CARTER, KENDRA D

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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07/30/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,999	<b>Applicant(s)</b> MILLER ET AL.	
	<b>Examiner</b> Kendra D. Carter	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u>                                    | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:8/18/04;11/24/04;12/1/05;1/11/06.

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species: IRM compound. The species are independent or distinct because the IRM compounds have different structures and hence are classified in different classes and subclasses.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1617

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

During a telephone conversation with Ted Ringsred on July 12, 2007 a provisional election was made without traverse to prosecute the IRM compound as the imidozoquinoline amine compound imiquimod, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**(1) Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11-16 of copending Application No. 11/091037 ('037).**

Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '037 teaches a method of reducing, reversing or preventing scarring of a subject's skin resulting from a surgical wound, the method comprising topically applying to the scarred skin at the site of the surgical wound an IRM compound in an amount effective to improve the quality of the skin (see claims 1 and 11). The IRM compound is an agonist of at least one TLR, specifically TLR7, TLR8 or both TLR7 and TLR8 (see claims 2, 3, 12 and 13). The method is administered via a topical application vehicle comprising a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil (see claims 4, 5, 14 and 15). The IRM compound is an imidazoquinoline amine, a tetrahydroimidazooquinoline amine, an imidazopyridine amine, and others disclosed in claims 6 and 16).

Art Unit: 1617

**(2) Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-7 of copending Application No. 11/358,017 ('017).**

Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '017 teaches a method of restoring at least a portion of diminished contact hypersensitivity administering an immune response modifier compound selected from the group consisting of an imidozoquinoline amine and others disclosed in claims 1 and 5. The immune response modifier compound is an agonist of at least one TLR, specifically TLR7, TLR8 or TLR9 (see claims 3 and 4). The method is administered via a topical application vehicle comprising a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil (see claims 6 and 7).

The application '017 does not specifically teach a method of improving skin quality, but upon treating a skin disorder such as contact hypersensitivity, one would improve the skin quality.

Art Unit: 1617

**(3) Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 10, 18, 19, 21, 25, and 27 of copending Application No. 10/808,004 ('004).**

Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '004 teaches a method of treating superficial basal cell carcinoma in a subject comprising administering an effective amount of the IRM compound imiquimod topically on the lesions (see claim 27). In regards to the IRM compound being an agonist of TLR7, TLR8 or both, this limitation is taught because the applicant's elected compound, imiquimod, is disclosed in claim 27 and thus has the same properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The application '004 does not specifically teach a method of improving skin quality, but upon treating the skin disorder superficial basal cell carcinoma, one would improve the skin quality.

The application '004 also does not specifically teach that the application vehicle comprises a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil. To one of ordinary skill in the art would find it obvious to formulate the topical method of '004 to comprise a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil because these are forms of topical formulations.

***Claim Rejections - 35 USC § 112***

I. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if the changes in the dermis include all of the limitations of claim 11 (i.e. diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis) or any of the above limitations or a combination thereof. The language "a combination thereof" reads on the

Art Unit: 1617

changes in the dermis being any one of the above or a combination thereof, but the word "and" reads on all of the above changes, which would not need the language of "combinations thereof" because all of the changes are required. For compact prosecution, the Examiner has interpreted the claims to read on the changes in the dermis including diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis or a combination thereof.

II. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**(1) Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating (i.e. reversing) changes in the dermis, does not reasonably provide enablement for prancing changes in the dermis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to using the invention commensurate in scope with these claims.**

The instant claim is drawn to a method of improving the quality of facial skin comprising topically applying to facial skin an IRM compound in an amount and for a period of time sufficient to prevent changes in the dermis. The instant specification fails

Art Unit: 1617

to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 11 is drawn to "a method for improving the quality of facial skin comprising: topically applying to facial skin an IRM compound in an amount and for a period of time sufficient to reverse or prevent changes in the dermis, where the changes in the dermis include diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, and combination thereof, and wherein the IRM compound is an imidazoquinoline amine, a tetrahydroimidozoquinoline amine, an imidazopyridine amine, a 1,2-bridged imidazoquinoline amine, a 6,7-fused cycloalkylimidazopyridine amine, an imidozonaphthridine amine, a tetrahydroimidazonaphthyridine amine, an oxazoloquinoline amine, a thiazoloquinoline amine, an oxazolopyridine amine, a

Art Unit: 1617

thiazolopyridine amine, an oxazolonaphthyridine amine, a thiazolonaphthyridine amine, or a combination thereof.”

(2) The breadth of the claims:

Claim 11 embraces preventing changes in the dermis, where the changes in the dermis include diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, and combination thereof. This reads on completely preventing the above changes in the dermis.

(3) The state of the prior art:

The state of the art regarding completely preventing changes in the dermis is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability of completely preventing changes in the dermis is relatively low. Therefore, to one skilled in the art, prevention of changes in the dermis is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the complete prevention of changes in the dermis, where the changes in the dermis include diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, and combination thereof is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that completely prevent changes in the dermis. The specification teaches that wrinkles, which are due to diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of dermis, reduction in subcutaneous adipose tissue, and excessive deposition of abnormal elastic materials in the upper dermis was treated but not prevented (see specification pages 15 and 16, example 3). One would need to provide data indicating that the subject applied the invention and never had changes in the dermis, where the changes in the dermis include diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, and combination thereof. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on the complete prevention of changes in the dermis, where the changes in the dermis include diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, and combination thereof. As discussed above the specification fails to provide any support for completely preventing changes in the dermis. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating (or reversing) changes in the dermis, where the changes in the dermis include diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, and combination thereof, but not for preventing the above changes in the dermis.

**(2) Claims 1, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving skin quality comprising topically applying to the skin imiquimod, does not reasonably provide enablement for all IRM compounds. The specification does not enable any**

Art Unit: 1617

**person skilled in the art to which it pertains, or with which it is most nearly connected, to using the invention commensurate in scope with these claims.**

The instant claim is drawn to a method of improving the quality of facial skin comprising topically applying to facial skin an IRM compound. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to "a method for improving skin quality comprising topically applying to the skin an IRM compound in an amount effective to improve the quality of the skin."

(2) The breadth of the claims:

Claim 1 embraces improving skin quality comprising topically applying to the skin an IRM compound. This reads on all IRM compounds effectively being able to improve the quality of the skin.

(3) The state of the prior art:

The state of the art regarding all IRM compounds effectively being able to improve the quality of the skin is very low or do not exist. For instance, Kim et al. (US 5,576,018) teaches that the immune response modifier (IRM) compounds such as lymphokines are used for the treatment of neurological disorders (see title, column 6, lines 46-53, and column 9, table 1, line 31). Kim et al. does not teach that all IRM compounds improve the quality of the skin, nor does Kim et al. teach any of the applicant's compounds as IRM compounds. Thus, there are IRM compounds that are taught by the prior art that do not improve the quality of skin.

(4) The predictability or unpredictability of the art:

The predictability of all IRM compounds effectively being able to improve the quality of the skin is relatively low. Therefore, to one skilled in the art, improving the quality of the skin with all or any IRM compounds is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

Art Unit: 1617

## (6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to all IRM compounds effectively being able to improve the quality of the skin is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that completely prevent changes in the dermis. The specification teaches the treatment of rough, dry, or scaly skin, wrinkles, and mottled pigmentation with a 5% cream of imiquimod, the imidazoquinoline amine IRM (see pages 13-17). Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

## (7) The quantity of experimentation necessary:

The instant claims read on all IRM compounds effectively being able to improve the quality of the skin. As discussed above the specification fails to provide any support for all IRM compounds effectively being able to improve the quality of the skin. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. One would need to perform further experimentation to acquire the effectiveness and the effective amounts of each IRM compound in prior art in order to practice the invention. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for improving skin quality comprising topically applying to the skin imiquimod, but not for all IRM compounds.

**(3) Claims 2, 3 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description on how to administer all of the different types of classes of IRM compounds (even those that are TLR7 agonist) other than imiquimod. For instance, the differences in structural features of the different classes of compounds disclosed in claims 6-11 will result in different reactivity, solubility, bioavailability, etc. Thus, by virtue of the different structures and reactivity of these compounds, the efficacy will inherently be different. One would need to perform further experimentation to acquire the effectiveness and the amounts of each IRM compound in prior art in order to practice the invention. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**(1) Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maibach et al. (US 2003/0072724 A1) in view of Raz et al. (US 2004/0248837 A1).**

Maibach et al. teaches a treatment of an individual predisposed to or afflicted with skin hyperpigmentation, and comprises topically administering to the individual's affected skin area a pharmaceutical formulation containing a therapeutically effective amount of an agent active for treating skin hyperpigmentation (see page 4, paragraph 44, lines 1-7). A preferred embodiment is the treatment of age spots, which is age-

Art Unit: 1617

related and hence is common among the elderly (see page 5, paragraph 45, lines 5-8). Active agents include any compound that effectively treats warts such as imiquimod (see page 8, paragraph 92, lines 1-3 and 7; addresses claims 1, 6, 4, 7, 9 and 10). Treatment is to improve or remediate damage, which is exemplified in examples 4 and 5 by the lightened skin regaining essentially normal skin color after eight weeks of treatment (i.e. visibly reducing a skin change associated with aging and improving the quality of the skin; addresses claims 1, 7, 9 and 10). The formulation may be in any form suitable for application to the body surface such as a cream, lotion, solution, gel, ointment, paste, or the like (see page 9, paragraph 100, lines 1-4; addresses claim 5).

Maibach et al. does not teach the IRM compound imiquimod is an agonist of at least one TLR, specifically TLR7, TLR8 or both.

Raz et al. teaches that a TLR agonist is any compound or substance that functions to activate a TLR, e.g. to induce a signaling event mediated by a TLR signal transduction pathway. An example of a TLR ligand-mediated signal transduction event is activation of the IL-1R-associated kinase IRAK (see page 6, paragraph 68, lines 3-7). TLR7 ligands include imidazoquinoline compounds such as imiquimod (see page 7, paragraph 77, lines 1-6).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Maibach et al. and an agonist of at

Art Unit: 1617

least one TLR, specifically TLR7, because of the following teachings: Maibach et al. teaches a method to treat age-spots comprising imiquimod and Raz et al. teaches that imiquimod is an agonist of TLR7. In addition, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

**(2) Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,335,023 B1) in view of Maibach et al. (US 2003/0072724 A1).**

Yu et al. teaches a method of treating cosmetic conditions or dermatological disorders comprising topically applying a topically acceptable vehicle, at least one compound selected from the group consisting of oligosaccharide aldonic acids, and a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42). Cosmetic conditions or dermatological disorders include changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40). The compositions may be formulated as a solution, gel, lotion, cream, ointment, spray, or other forms acceptable for use on skin (see column 17, lines 49-52). Yu et al. teaches that with increasing age and exposure of human to sun and other environmental

Art Unit: 1617

traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42; addresses claim 11).

Yu et al. does not specifically teach applying imiquimod to treat of wrinkles.

Maibach et al. teaches a treatment of an individual predisposed to or afflicted with skin hyperpigmentation, and comprises topically administering to the individual's affected skin area a pharmaceutical formulation containing a therapeutically effective amount of an agent active for treating skin hyperpigmentation (see page 4, paragraph 44, lines 1-7). A preferred embodiment is the treatment of age spots, which is age-related and hence is common among the elderly (see page 5, paragraph 45, lines 5-8). Active agents include any compound that effectively treats warts such as imiquimod (see page 8, paragraph 92, lines 1-3 and 7). Treatment is to improve or remediate damage, which is exemplified in examples 4 and 5 by the lightened skin regaining essentially normal skin color after eight weeks of treatment (i.e. visibly reducing a skin

change associated with aging and improving the quality of the skin; addresses claims 1, 7, 9 and 10).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and applying imiquimod to treat of wrinkles because of the following teachings: (1) Yu et al. teaches a method of treating cosmetic conditions or dermatological disorders changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40), with a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42); (2) Maibach et al. teaches a treatment for the age related skin condition age-spots or hyperpigmented skin, in which the active ingredient is imiquimod (see page 5, paragraph 45, lines 5-8 and see page 8, paragraph 92, lines 1-3 and 7); and (3) Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42). Thus, one would be motivated to try the treatment of age related skin conditions such as wrinkles with the active ingredient imiquimod, because it also treats the age-related skin condition of age-

Art Unit: 1617

spots or hyperpigmented skin, which also results in the fibers of the dermis becoming smaller and sparser with increasing age.

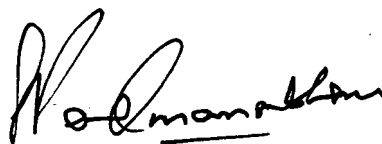
**Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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KDC

  
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